

REMARKS

Claims 1, 17, and 21 are amended and claims 1, 6-17, 19-21, 24-26 are now pending in the application. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

Rejections Under 35 U.S.C. §103

The Office Action rejects claims 1, 6-16, and 24 under 35 U.S.C. §103(a) over WO 0078286 to Wu et al. ("Wu") in view of U.S. Patent No. 6,296,156 to Lasserre et al. ("Lasserre"). The Office Action also rejects claims 17, 19-21 and 25-26 over Wu in view of U.S. Patent No. 6,668,439 to Ablanalp et al. ("Ablanalp"). The rejections are respectfully traversed.

By way of example, present claim 1 recites, *inter alia*:

a rubber valve gasket connected to the cap and or valve;
an aerosol canister connected to the cap, said aerosol canister further having an outwardly [[a]] rolled neck or full rollover rim in contact with said rubber valve gasket to reduce the compression of the gasket and thereby reduce the release of gasket rubber components; and
a pressurized medicinal aerosol solution formulation . . . in contact with said rubber gasket . . . , said medicinal aerosol solution formulation comprising an active

ingredient subject to a degradation by means of peroxides and/or other leachables from the gasket rubber

Thus, the objective technical problem to be solved by the features of present claim 1 is to provide a medicinal aerosol solution formulation product with improved chemical stability by reducing the compression of a rubber gasket that contacts the medicinal aerosol solution formulation. It is important in the presently claimed embodiment that the formulation is in contact with the rubber of the gasket, which is thus part of the internal coating of the container. The solution to the stability problem of the active ingredient subject to a degradation by means of components which may be released by the gasket rubber, is the use of a canister having a rolled neck or a full rollover rim.

In addition, the embodiment of presently claimed 1 involves a “metering valve” and a pressurized formulation in the cannister. Not all cannister valves and dispenser systems are structured the same, and metering valves in particular as described and claimed are designed to have rubber gaskets used to seal the pressurized cannister. The rubber gaskets as claimed contact the formulation in the cannister.

The Examiner attention is directed toward the results presented in the Example 4 of the present specification. Specifically, it is clearly demonstrated in Tables 4 and 5 of the present application that the stability of the solution of an active medicament stored in cans finished with a rolled neck is greatly improved, in comparison with cut edge cans of Table 3. Only the present inventors have realized that not only the use of a non-metal interior surface is necessary to reduce chemical degradation of the medicament, but cans with a rolled neck are also required because of the rubber gasket that contacts the material.

In direct contrast, *Wu* is a device having a metered valve and uses a gasket 30 to seal the container 16 to the metering valve 18 but is concerned with the problem of chemical degradation of a 20-ketosteroid having an OH group at the C-17 or C-21 position in a medicinal aerosol solution formulation based on a hydrofluorocarbon (HFC or HFA) propellant. *Wu* found that the chemical degradation was due to the contact of the solution with a metal container and to the formation of metal oxides on the interior surfaces of the metal canister. *Wu* teaches to coat the internal surfaces of the aerosol canister as well as the surfaces of any other metal component in contact with the formulation, such as the valve, with an inert material, so as to reduce reaction of the 20-ketosteroid with metal oxides from the container.

Therefore, according to the teaching of *Wu*, the chemical degradation problem of the 20-ketosteroid is basically due to the interaction with a metal. There is no indication in *Wu* of a further problem of degradation.

Wu also provides description of metered dose inhalers (MDIs) commonly used for the delivery of medicinal aerosol products, with a standard cut edged opening. MDIs comprise a container equipped with a metering valve. The valve includes a gasket which is, at least partially, in contact with the formulation (see Figures 1 and 2). In fact, *Wu* is so much concerned with the problem of minimizing the contact of the formulation with metal components that he recommends the use of a particular kind of gasket 30, disclosed in Figure 2, to increase the surface contact of the gasket and prevent contact of the formulation with the metal (see page 6, lines 18 to 26).

Therefore, *Wu* does not appreciate at all the problem overcome by the present invention, of the possible migration of components from the rubber of the gasket to the solution, which may influence the chemical stability of the steroid in the formulation. Further, as also noted by the

Examiner, *Wu* does not teach or suggest a rolled neck canister. In fact, such a rolled neck cannister would tend to increase, not decrease the surface area of the metal container and thus defeat the objective of *Wu* of reducing metal components that contact the formulation.

Nowhere does *Wu* teach or suggest that there may be a problem with leachables from the rubber gasket or that such a problem was caused by minor damages or compression of the gasket by the end of the cut-end canister utilized in the art.

Wu cannot therefore by itself obviate the pending claim 1.

Lasserre cannot overcome the deficiencies of *Wu*. *Lasserre* discloses ways of mounting a dispensing valve on a container. Col. 2, ll. 39-51. To this aim, it proposes a dispenser wherein the open end of a container is closed by a cup. The cup bears a first mounting means having a U-shaped peripheral portion 6 which is radially deformable. A rolled neck on the container fits in the U-shape to form a secure connection. When a locking ring 16 is introduced into a groove 12, it outwardly deforms the peripheral portion 6 of the cup against the rolled neck of the container to provide a leaktight closure. Col. 4, l. 55 to col. 5, l. 24; col. 5, l. 54-65. Thus, as clearly seen by the dotted lines in Figs. 1 and 2, the cup is pressed against the container such that little, if any, composition in the container contacts the seal 25.

The open edge of the container of *Lasserre* can be shaped in various ways: as an outwardly rolled neck, an inwardly rolled neck or as a cutted neck having an external screw thread (see Figures 1-6 and claim 15). Regardless, the form of the container rim is particularly selected in connection with the corresponding features of the cup. That is, *Lasserre* does not teach a rolled rim in the abstract, but rather teaches a rolled rim that mates in a corresponding U-shaped receiving portion of the cup. There is no indication that the shape of the rim may perform other functions or be used in any manner except in conjunction with a design that puts

the rim in a shape that fills the U-shaped portion of the cup to provide resistance to the outward pressure provided by the locking ring 16. Indeed, if the rolled rim (or other shape) did not fill the U-shaped portion, or if the U-shaped portion was absent, the device would be dysfunctional.

Further, *Lasserre*'s products are dispensed in the form of a jet of liquid, gel, spray or foam/mousse (column 1, lines 15-21). A dispenser of this kind does not make use of a metering valve, but rather use a dispensing valve of the type illustrated in Fig 1. These kinds of valves are not provided with a sealing gasket, but are rather fixed into the mounting cup by means of an annular bulge 30 which collaborates with a complementary groove 28 made on the internal face of the mounting means 10 (column 5, lines 28-30). The only elastomeric portion in *Lasserre*'s containers is the elastomeric seal 25 placed between the cup 5 and the plate 6b to provide sealing between the upper part of the neck of the container and the cup (column 5, lines 16-18) or, as in Fig 1, an annular seal 7 between the valve body 2c and transverse wall 10b of the cup 5 (column 5, lines 44-46). In other words, no elastomeric seal is in contact with the product.

Lasserre in no way discloses or suggests a rubber valve gasket in contact with the inside formulation and the use of containers with an outwardly rolled neck to avoid compression or damages of the sealing gasket which may favour migration of rubber components to the formulation.

Therefore, one skilled in the art would have no reason to select the container of *Lasserre* since *Lasserre* uses its container in conjunction with a necessary adjoining cup design and in conjunction with a different valve type that does not use a sealing gasket of the kind presently disclosed and claimed. Instead, one skilled in the art would understand that *Lasserre*'s rolled rim on the canister is to be used with a correspondingly designed cup in a unified design.

Abplanalp also cannot cure the deficiencies of *Wu*. *Abplanalp* generally refers to valve mounting assemblies for aerosol containers, commonly referred to as “mounting cups.” More particularly *Abplanalp* relates to a mounting cup for aerosol containers with an improved type of gasket that forms the seal between the perimetrical rim of the mounting cup and the bead of the aerosol container. As clearly illustrated in Figures 1 and 2, the mounting cup 14 includes a body portion 20 terminating in a radially outwardly channel portion 22 designed to receive the rim or bead 34 extending around opening 32 of a container. As with *Lasserre*, the rounded rim or bead 34 is configured to fill a receiving U-shaped portion 22 as a mounting mechanism. A gasket 64 is disposed between bead 34 and the under surface of channel 22 of the mounting cup (column 5, lines 41-63). However, neither this gasket 64 or any other elastomeric material in contact with the product contained within the container. As a matter of fact, the function of the gasket is to guarantee an effective seal between the mounting cup and the container bead and for this purpose, the gasket is positioned in the interface between the mounting cup and the container bead (column 1, lines 47-51) .

Further, the bead 64 is designed to be used with the corresponding U-shape 22, not alone and so one would not be motivated to use it with any other structure that what is disclosed therein.

Therefore, there is nothing in *Abplanalp* which can cure the basic deficiencies of *Wu* and *Lasserre*.

For at least these foregoing reasons, the Applicants respectfully submit that the present claim 1 is patentable over the cited references. At least similar reasons to the foregoing, independent claims 17 and 21 and all the pending dependent claims are also patentable over the cited references. The prompt removal of the rejections is therefore respectfully requested.

Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited. Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Any additional fees incident to this Amendment may be charged to Deposit Account No. 08-2665.

DATED this 16th day of July, 2007.

Respectfully submitted,

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